UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
	)	Subcategory No. 06-11337
THIS DOCUMENT RELATES TO:	)	
United States ex rel Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation Civil Action No. 09-CV-10547	)	Hon. Patti B. Saris
United States ex rel Ven-A-Care of the Florida Keys, Inc.v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation Civil Action No. 00-10698	)	

COMMONWEALTH OF MASSACHUSETTS' OPPOSITION TO JOINT MOTION FOR APPROVAL OF SETTLEMENT BETWEEN CALIFORNIA, FLORIDA, AND VEN-A-CARE AND THE SCHERING/WARRICK DEFENDANTS

INTRODUCTION

Defendants Schering-Plough Corporation, Schering Corporation and Warrick Pharmaceuticals Corporation (collectively "the Schering/Warrick defendants") have entered into a Settlement Agreement with the Relator, Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care"), which is conditioned on this Court making certain "findings" relating to Schering brand drugs, among other things. (Settlement Agreement, Dkt. No. 6173-2, ¶ III.6, pp. 8-10.) In the Settlement Agreement Ven-A-Care purports to release "the federal-share of any claim brought by a state arising out of or related to the Covered Conduct or Covered Drugs." Id.

at ¶ III.5, p.8. The settling parties have jointly moved this Court to approve the Settlement Agreement, arguing it is fair, adequate and reasonable. Joint Memorandum in Support of Motion for Approval of Settlement, Dkt. No. 6360, pp.19-24.

As discussed in detail below, the Commonwealth of Massachusetts ("the Commonwealth") opposes the motion to approve this Settlement Agreement. A False Claims Act (FCA) *qui tam* action cannot be voluntarily dismissed, as is contemplated by this Settlement Agreement, without the consent of the Attorney General, who has withheld his consent to this agreement. The Commonwealth is a sovereign state, which has sued the Schering/Warrick defendants based on the Massachusetts FCA, among other causes of action, and Ven-A-Care has no authority to release any portion of the Commonwealth's case. The "findings" which the Schering/Warrick defendants ask the Court to make are nothing less than advisory opinions and beyond the Court's Article III authority. If the Court had authority to reach the merits of the Settlement Agreement, it should reject it because it is neither fair, adequate nor reasonable.

ARGUMENT

I. The False Claims Act Gives The Attorney General Veto Authority Over Relator Negotiated Settlement Agreements.

The Relator has brought these actions pursuant to 31 U.S.C. §3730(b) (1), which authorizes private persons to bring civil actions for violation of the federal False Claims Act "for the person and for the United States Government." Thus, there are two, separate causes of action, one for the *qui tam* Relator and one for the United States Government. *Hughes Aircraft Company v. United States ex rel. Schumer*, 520 U.S. 939, 950 (1997) ("the 1986 amendment [to the FCA] essentially creates a new cause of action.") The Relator can release its own cause of action, but it cannot release the United States Government's cause of action without the consent of the Attorney General. 31 U.S.C. §3730(b)(1) ("[t]he action may be dismissed only if the court

and the Attorney General give written consent to the dismissal and their reasons for consenting."); *United States ex rel. Eisenstein v. City of New York*, 556 U.S.__, 129 S. Ct. 2230, 2234 (2009) (rights retained by U.S. when it does not intervene include "vetoing a relator's decision to voluntarily dismiss the action, §3730(b)(1)"); *United States v. Health Possibilities, P.S.C.*, 207 F.3d 335, 342 (6th Cir. 2000) ("[t]he government's status as the real-party -in-interest renders a relator's unilateral attempt to settle akin to impermissibly bargaining away the rights of a third party"); *Searcy v. Phillips Electronics North America Corporation*, 117 F.3d 154, 155(5th Cir. 1997) (31 U.S.C. §3730(b)(1) is "unambiguous in its declaration that courts may not grant a voluntary dismissal in a False Claims Act suit unless the U.S. Attorney General consents to the dismissal*"); United States ex rel. Globe Composite Solutions, Ltd. v. Solar Construction Inc.*, 528 F. Supp. 2d 1, 3 (D. Mass. 2007) (Tauro, J.) ("the Government must consent to all dismissals in a qui tam action brought by a private person, even voluntary dismissals by the plaintiff-relator"); *see also, In Re Pharmaceutical Industry Average Wholesale Price Litigation*, 538 F. Supp. 2d 392, 397-98 (D. Mass. 2008)("several circuits have . . . found that the government's consent to dismissal is required even after the government declines to intervene*"); but see, United States ex rel. Killingsworth v. Northrop Corp.*, 25 F. 3d 715, 722(9th Cir. 1994)("the consent provision contained in §3730(b)(1) applies only during the initial sixty-day (or extended) [seal] period.")

The requirement that the Attorney General consent to the voluntary dismissal of a FCA *qui tam* action is based on sound public policy. Relators often have interests in settlements which are adverse to the interests of the United States. The scope of the release is one of those interests. As the Fifth Circuit said, in rejecting a FCA *qui tam* settlement to which the Attorney General did not consent, because of the scope of the release:

> This case presents a relator who allegedly wants to trade on the defendants' desire to maximize preclusive effects. Plaintiffs ordinarily prefer to keep their options open; agreeing not to bring future suits can be costly. In *qui tam* litigation, however, there is a danger that a relator can boost the value of settlement by bargaining away claims on behalf of the United States.

Searcy v. Phillips Electronics North America Corporation, 117 F.3d at 160. This inherent conflict is precisely what is at issue in this case. The Schering/Warrick defendants have insisted on overly broad release language from Ven-A-Care, and other non-monetary terms such as "findings" relating to Schering drugs, as a condition precedent to paying any money. These concessions in no way impact the Relator's monetary recovery. They are, however, adverse to the interests of United States. For this reason Congress has required that the Attorney General consent to the dismissal of the action before such concessions will be implemented. This Court needs to tell the Schering/Warrick defendants that in the Court's view it cannot approve a voluntarily dismissal of these FCA *qui tam* actions without the consent of the Attorney General.

II. The Commonwealth of Massachusetts Is A Sovereign State and Ven-A-Care Has No Authority To Release Any Portion of the Commonwealth's Case.

The Commonwealth has sued the Schering/Warrick defendants for violation of the Massachusetts FCA, among other causes of action, in connection with their price reporting practices on certain generic albuterol drugs. Civil Action No. 03-11865-PBS. In this action the Commonwealth seeks to recover the difference between what it actually paid to pharmacists for prescriptions filled with Warrick albuterol products and what it would have paid had the Schering/Warrick defendants reported true prices to First DataBank. At all relevant times Massachusetts had a Federal Medical Assistance Percentage (FMAP) of 50%, meaning that the federal government reimbursed Massachusetts for 50% of its Medicaid expenditures, including the excess amounts it paid for Warrick albuterol. The Massachusetts FCA meets the requirements of the Deficit Reduction Act of 2005, which provides for a 10% bonus to states for

FCA actions to recover Medicaid overpayments. See 42 U.S.C. §1396h(a). Thus, the Commonwealth will need to refund to the federal government only 40%, not 50%, of whatever it recovers from the Schering/Warrick defendants in its pending Massachusetts FCA action.[1]

The Settlement Agreement at issue here provides, in part:

> the Relator on behalf of the United States and on behalf of the Relator … fully and finally release[s] … Schering/Warrick … from any claim, action, suit or proceeding … that the Relator has asserted or could have asserted on behalf of the United States or on its own behalf arising out of or related to the Covered Conduct for the Covered Drugs … during the Relevant Period, *including but not limited to the federal-share of any claim brought by a state arising out of or related to the Covered Conduct or Covered Drugs.*

Settlement Agreement, Dkt. No. 6173-2, p.8, ¶5. This purported release is beyond the Relator's authority to grant. The Relator is not a party to the Commonwealth's case and can not release any portion of the Commonwealth's damages. The Massachusetts FCA has a *qui tam* provision but the Relator has not chosen to utilize it. M. G. L. ch.12 §5C (2). Having failed to invoke the *qui tam* provisions of the Massachusetts FCA, Ven-A-Care can grant no release relating to any portion of the Commonwealth's case.

The Schering/Warrick defendants assert in their Memorandum that:

> [the] objecting parties apparently agree that the settlement and release …, if approved, would extinguish all rights to the recovery of the federal-share of any alleged Medicaid overpayment brought by any state.

Jt. Memorandum, Dkt. No. 6360, p.6. This assertion is wrong. The Commonwealth does not agree that the release provisions of the Settlement Agreement would extinguish any portion of its

[1] The Schering/Warrick defendants assert that the Commonwealth "should be economically indifferent" whether it recovers all of its damages, and then refunds a portion of those damages to the federal government, or whether the so-called "federal-share" is recovered in a seperate federal action and the Commonwealth is permitted to keep everything it recovers in its own action. Jt. Memorandum, Dkt. No. 6360, p.14. This assertion is incorrect. The existence of the 10% Deficit Reduction Act of 2005 bonus means that, at the very least, the Commonwealth has a 10% stake in recovering damages in its FCA action, as opposed to having those federal damages paid directly to the U.S. in a federal *qui tam* action.

claims in its pending civil action. Should the Schering/Warrick defendants settle with the federal government and make any payment attributable to Massachusetts reimbursements to pharmacists for Warrick albuterol drugs, then the Schering/Warrick defendants will be able to offer evidence at trial of such settlement payments, in mitigation of their damages in the Commonwealth's case. Such mitigation evidence will only be applied, however, after the single damages have been trebled. M.G.L. ch.12 §5B(9) (any person who violates §5B "*shall* be liable to the commonwealth …for a civil penalty … plus three times the amount of damages"); United States v. Bornstein, 423 U.S. 303, 316, 96 S. Ct. 523, 531 (1976) ("the Government's actual damages are to be doubled before any subtractions are made for compensatory payments previously received by the Government from any source.")

III. The "Findings" Which The Schering/Warrick Defendants Ask This Court To Make Are Advisory Opinions Which Are Beyond The Court's Authority To Make.

The Schering/Warrick defendants have conditioned the Settlement Agreement on this Court making certain "findings of fact" relating to certain Schering brand name drugs and other topics. Settlement Agreement, Dkt. No. 6173-2, ¶ III.6. pp.8-10. The Settling Parties have submitted a proposed Order containing the proposed findings. Proposed Order, Dkt. No. 6173-2, Exhibit C. The proposed findings include

- government payors, such as Medicaid, did not reasonably consider published AWPs that were generally within 30% of the average selling price of that drug … to constitute a false or fraudulent statement, or to be misleading, deceptive or unfair.

- government payors could not have reasonable considered the published WAC for a brand drug where substantial sales were made at WAC (i.e., more than 50% of a drug's sales occurred within 5% of WAC) to constitute a false or fraudulent statement or to be misleading, deceptive or unfair.

- that none of the WACs or AWPs for the Schering-brand drugs … constituted false or fraudulent statements, or were misleading, deceptive or unfair.

Id. at ¶ 3, 4 and 5.

These proposed "findings" are nothing less than advisory opinions. There is no dispute between Ven-A-Care and the Schering/Warrick defendants relating to these proposed findings. Ven-A-Care agreed to amend its complaint to add a paragraph which alleges:

> the states' Medicaid programs did not incur substantial damages from Schering Brand Drugs because [the Schering/Warrick defendants] did not materially misstate the drug price report for those drugs.

Amended Complaint, Dkt. No. 6292, ¶ 76. Not surprisingly, the Schering/Warrick defendants consented to this amendment. Dkt. No. 6286. When the Court asked counsel for the Schering/Warrick defendants whether they would be submitting a brief relating to the approval of the Settlement Agreement, separate from Ven-A-Care, counsel responded in the negative, noting "We're on the same side." Transcript, 7/24/09 Hearing, 19:3. Given that Ven-A-Care and the Schering/Warrick defendants "are on the same side," there are no justiciable issues and the proposed findings of fact are advisory opinions.

Federal courts do not issue advisory opinions. *Maher v. Hyde*, 272 F.3d 83, 86 (1st Cir. 2001). Article III of the Constitution restricts federal courts to the resolution of actual cases and controversies. The case or controversy requirement under Article III "limit[s] the business of federal courts to questions presented in an adversary context." *Overseas Military Sales Corp. v. Giralt-Armada,* 503 F.3d 12, 16-17 (1st Cir. 2007); *see also Flast v. Cohen,* 392 U.S. 83, 95, 88 S.Ct. 1942 (1968) ("Federal courts are limited to questions presented in an adversary context.")

In order for a case to be justiciable and not an advisory opinion, there must be an actual dispute between adverse litigants. *United States v. Johnson*, 319 U.S. 302, 304, 63 S.Ct. 1075 (1943). To determine whether there exists a justiciable controversy under Article III, a court must decide whether there exists "a live and acute controversy that must be resolved," *Steffel v.*

Thompson, 415 U. S. 452, 459, 94 S. Ct. 1209, 1216, 39 L. Ed. 2d 505 (1974). Federal courts are not empowered to give plaintiff advisory opinions where there is no actual controversy. *Shell Oil Co. v. Noel*, 608 F.2d 208, 211 (1st Cir.1979).

There is simply no "live and acute controversy that must be resolved" between Ven-A-Care and the Schering/Warrick defendants relating to these proposed findings, because, as Schering/Warrick's counsel aptly noted, they are "on the same side." The participation of the United States or the Commonwealth, as objectors to the Settlement Agreement, does not create the required adversarial dispute. In *United States v. Johnson*, 319 U.S. 302, 63 S. Ct. 1075 (1943) the Supreme Court refused to enter judgment on the merits in a suit between a tenant and a landlord under the Emergency Price Control Act of 1942. The Government intervened in the case, arguing there was no case or controversy because the defendant encouraged the plaintiff to sue and had hired the plaintiff's counsel. *Id*. at 303-04. The Court agreed with the Government, notwith standing the intervention of the Government, noting the absence of an "honest and actual antagonistic assertion of rights" to be adjudicated, which was "a safeguard essential to the integrity of the judicial process." *Id*. at 305. So likewise here there is no "honest and antagonistic assertion of rights" between the Schering/Warrick defendants and Ven-A-care relating to any of these proposed findings.

IV. The Settlement Agreement Is Neither Fair, Adequate Nor Reasonable and Should Be Rejected.

The Settlement Agreement provides for the Relator to dismiss the two pending federal *qui tam* actions with prejudice. Settlement Agreement, Dkt. No. 6173-2 ¶ 7, p.10. Such a voluntary dismissal requires the consent of the Court. 31 U.S.C. §3730(b)(1). The FCA does not contain any provision which expressly provides what the legal standard is that the Court should apply in deciding whether to consent. The FCA does provide that the United States may

dismiss a *qui tam* action over the objection of the Relator if the Court finds, after a hearing, that the proposed settlement is "fair, adequate, and reasonable under all the circumstances." 31 U.S.C. §3730(c)(2)(B). Fair, reasonable and adequate is also the standard for the Court's review of proposed class action settlements. Fed.R.Civ. P.23(e)(2). Ven-A-Care and the Schering/Warrick defendants have proposed a "fair, adequate and reasonable under all the circumstances" standard in this case. The Commonwealth believes that the Court need not even reach this issue, because the Attorney General does not consent to these dismissals and the Settlement Agreement calls for advisory opinions. If the Court does reach this issue, the Commonwealth does not object to the "fair, adequate and reasonable under all the circumstances" standard. Consistent with class action practice, the proponents of the settlement have the burden to establish that the settlement is fair, adequate and reasonable. *Rolland v. Patrick*, 562 F.Supp.2d 176, 178 (D. Mass. 2008). This standard is a flexible one focused on the reasonableness of the settlement. *New England Carpenters Health Benefits Fund v. First Data Bank, Inc.*, 602 F.Supp.2d 277, 280-81 (D. Mass. 2008).

This Settlement Agreement is neither fair, reasonable nor adequate. It is certainly not fair to the states still litigating with the Schering/Warrick defendants. *New England Carpenters Health Benefit Fund*, 602 F.Supp.2d at 281 (where the rights of third parties are affected "their interests too must be considered.") The Settlement purports to release a portion of their claims against the Schering/Warrick defendants, in an action in which they are not a party. In essence, this Settlement Agreement is an attempt by the Schering/Warrick defendants to force the states who are still litigating against them to litigate in this Court, in the context of a settlement approval hearing, whether Schering brand prices are false, fraudulent, unfair, misleading or deceptive and whether any Medicaid liability under any state statute can result from Schering's

price reporting practices for its brand drugs. This is unfair and amounts to a renewed effort to remove state court AWP actions to federal court.

This Settlement Agreement is also not reasonable. The essence of the pending *qui tam* actions, prior to the execution of Settlement Agreement, was the Schering/Warrick defendants' Medicaid liability for its price reporting practices relating to Warrick's albuterol drugs. Pursuant to this Settlement Agreement, Ven-A-Care, with the Schering/Warrick defendants' consent, added 22 Warrick generic drugs and 29 Schering brand name drugs. Amended Complaint, Dkt. No. 6292, Exhibits E and F. Ven-A-Care then purported to release on behalf of the United States any claim the Relator asserted, or could have asserted, relating to all of these additional drugs. Such last minute manipulations of a release are not reasonable. *Searcy v. Phillips Electronics North America Corp.*, 117 F.3d at 160 ("In *qui tam* litigation, however, there is a danger that a relator can boost the value of settlement by bargaining away claims on behalf of the United States.")

Finally, the settlement amount, $55 million, is not adequate. Pursuant to the Settlement Agreement the $55 million payment by the Schering/Warrick defendants is intended to cover all of their liability to the United States, for all of their damages to the Medicaid program, nationwide, from 1991 up to June 25, 2009, for all of the Schering and Warrick drugs, plus all of their liability to the states of California and Florida, for damages to their Medicaid programs, for the same drugs and time periods, along with all of the costs, expenses and attorneys fees due to the Relator and its counsel. Settlement Agreement, Dkt. No. 6173-2, ¶s 1-3. The Relator, California and Florida have entered into an Allocation Agreement which provides that the United States would recover only $23.47 million, from which the United States would be obligated to

pay a relator's share of between 25 and 30 percent. 7/24/09 Hearing Transcript, 35:15; 31 U.S.C. §3730(d)(2).

This amount, $23.47 million, is clearly inadequate. The damages to the Massachusetts Medicaid program alone (federal and state share), for only the Warrick albuterol drugs, for only the years 1995 to 2003, were $12.068 million. Expert Report of Dr. Raymond S. Hartman, C.A.No. 03-11865-PBS, Dkt. No. 460, p.188. Upon a finding of liability at trial, the Commonwealth is entitled to three times that amount, namely $36.2 million, plus civil penalties of at least $5,000 per false claim. The Massachusetts Attorney General's office has participated with other states in numerous global settlements with pharmaceutical companies in recent years. In these other national settlements the Massachusetts Medicaid drug utilization and damages figures have usually accounted for between 3 and 5 percent of the national total.

In attempting to justify the adequacy of the Settlement Amount the Settling Parties point to this Court's decisions regarding Schering and Warrick in the MDL class action trial and "litigation risks." Jt. Memorandum, Dkt. No. 6360, pp.20-21. Rather than adequacy, the Court's findings as to the Warrick drugs in the MDL trial demonstrate the inadequacy of the Settlement Amount. In connection with the MDL trial, this Court found:

- Schering and Warrick never lowered their reported AWPs despite offering significant discounts that reduced the ASPs. 491 F.Supp.2d 20, 70 (D. Mass. 2007).
- Schering and Warrick were well aware of the role that spread played in driving purchasing decisions for their products. *Id*. at 71.
- the spread on every Warrick albuterol NDC in every year were all over 100%, reaching 800% in 2003. *Id*. at 75.

Based on these finding the Court concluded

> Schering-Plough's subsidiary Warrick acted unfairly and deceptively by causing the publication of false and inflated average wholesale prices for its generic drug

> albuterol sulfate, which had mega-spreads between 100% and 800% throughout the class period. *Id*. at 31.

The Court found no damages as to Warrick only because the Medicare program reimbursed on the basis of the median AWP. *In Re Pharmaceutical Industry AWP Litigation*, 520 F.Supp.267, 273 (D. Mass. 2007). The Medicaid program, on the other hand, sets Estimated Acquisition Cost (EAC) for each Warrick product based on Warrick's reported prices.

The results of recent AWP trials also demonstrate the inadequacy of the recovery in this Settlement Agreement. The State of Alabama has recovered the following verdicts at trial in AWP cases:

AstraZeneca	$160 million
GlaxoSmithkline	$81 million
Novartis	$33 million
Sandoz	$78.4 million

Each of these trial verdicts included substantial punitive damage awards. Recognizing their vulnerability, the Schering/Warrick defendants recently paid an undisclosed amount to Alabama as part of an $89 million, six defendant settlement.

The Schering/Warrick defendants went to trial in October 2008 in Missouri. The jury returned a $9 million compensatory verdict. While the jury was deliberating on punitive damages the Schering/Warrick defendants settled for $31 million. The jury later indicated it would have returned a $100 million punitive damages verdict.

Kentucky recently won a $16 million verdict against Sandoz. In Wisconsin, a jury returned a $9 million verdict against Pharmacia. In both the Kentucky and the Wisconsin cases the jury found that civil penalties were appropriate. The jury found 2,900 violations in Kentucky, each subject to a $2,000 penalty, while the Wisconsin jury found 1.4 million false

price reports, each subject to a penalty of between $100 and $15,000. In both states the issue of civil penalties remain pending with the courts.

There is simply no way to justify $23.47 million as a fair, adequate or reasonable settlement of the Schering/Warrick defendants' Medicaid liability to the United States, nationwide, for all of the Schering and Warrick drugs for the years 1991 to 2009.

CONCLUSION

The motion to approve this Settlement Agreement should be denied. Without the consent of the Attorney General these actions cannot be voluntarily dismissed. The parties have attempted to obtain advisory opinions from this Court which they want to use in other state actions. The Settlement Agreement is unfair, unreasonable and the Settlement Amount is clearly inadequate.

Rejecting this Settlement Agreement will send a clear message to the Schering/Warrick defendants that if they really want finality they need to negotiate, in good faith, with the United States and the states with whom they still have cases pending, with a realistic view of their litigation exposure. The Commonwealth stands ready to engage in good-faith negotiations at any time.

Respectfully submitted,

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Dated: August 30, 2009

Certificate of Service

I hereby certify I have caused a copy of the foregoing Memorandum to be served on counsel for each other party in these actions by filing it electronically in the Court's CM/ECF system, this 30th day of August, 2009.

/s/Peter A. Mullin
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Assistant Attorney General